

**REMARKS**

Reconsideration and allowance of this application are respectfully requested. Currently, claims 1-10 are pending in this application.

**Rejections Under 35 U.S.C. §102 and 103**

Claims 1, 9 and 10 were rejected under 35 U.S.C. §102 as allegedly being anticipated by Kuth et al. (US '663, hereinafter "Kuth").<sup>1</sup> Applicant respectfully traverses this rejection.

Anticipation under Section §102 of the Patent Act requires that a prior art reference disclose every claim element of the claimed invention. See, e.g., *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1574 (Fed. Cir. 1986). Kuth fails to disclose every claim element of the claimed invention. For example, Kuth fails to disclose (or even suggest) "generating thermal information in relation to each of said spatial locations by employing said first x-ray image and said at least a second x-ray image, wherein said thermal information is indicative of relative magnitudes of temperature changes for each of said spatial locations throughout said tissue region of interest," as required by independent claim 1 and its dependents.

Independent claim 1 relates to a thermal treatment of a tissue region, wherein at least two X-ray images are acquired at different times in connection with the thermal treatment, wherein each of the X-ray images comprise X-ray image values corresponding with an array of spatial locations throughout a tissue region, and wherein the X-ray images are used to generate thermal information in relation to each of the spatial locations, said thermal information being indicative of relative magnitudes of temperature change. Further, independent claim 1 provides for spatial display of the thermal information for the array of spatial locations, wherein the noted relative

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<sup>1</sup> Applicant notes that Kuth was also cited in parent U.S. Application No. 09/566,958 (now U.S. Patent No. 6,684,097). See, for example, the Official Actions mailed 4/15/2003 and 8/12/2002 in parent U.S. Application No. 09/566,958.

magnitudes of temperature change (e.g., change occurring between two X-ray image acquisitions) throughout the tissue region are visually discernable.

Fig. 19B of the present application illustrates an exemplary approach for visually presenting relative temperature change magnitudes corresponding with the array of spatial locations throughout the tissue region. As illustrated, a range of shading, e.g., colors, is utilized in corresponding relation to a range of relative magnitudes. For instance, and as indicated by the scale on the right side of Fig. 19B, the color red indicates a high magnitude of temperature change, while the color blue indicates a lower magnitude of temperature change. Provision of such X-ray-derived thermal information allows medical personnel to readily assess the relative and spatial progression of tissular temperature change across a tissue region, e.g., regardless of whether tissue changes have occurred within such region.

The prior art fails to disclose or suggest the noted features. In particular, Kuth fails to disclose or suggest, *inter alia*, the generation or spatial display of thermal information for an array of spatial locations throughout a tissue region, wherein relative magnitude of temperature changes throughout the tissue region are visually discernable.

Pages 2-3 of the Office Action apparently alleges that column 4, lines 5-20 and lines 45-57 and column 4, line 45 to column 5, line 13 of Kuth discloses the above noted claim limitations. Applicant respectfully disagrees with this allegation. These referenced portions of Kuth are merely directed to a focus-correction functionality that is utilized prior to or after ultrasound treatment and that does not otherwise yield thermal information for an array of spatial locations through a tissue region as per the present invention. That is, the referenced portion of Kuth is only directed to the determination of the “position of...temperature change” (emphasis added). Applicant submits such determination is made for purposes of allowing a physician to

make positional corrections with respect to a “therapeutic effective region” and a “body region...to be treated.” See, e.g., column 1, lines 6-16 of Kuth. Moreover, in the display of Fig. 7 of Kuth, a theoretical focus zone “F” represents a desired target area for thermal treatment of a tumor “T”, and an actual focus zone “E” represents an area at which thermal treatment is targeted. By viewing such a display, a physician can purportedly compare the positions of “F” and “E” and make positional corrections to avoid focusing an ultrasound-heating device at healthy tissue. Of note, the area and zones of Fig. 7 are displayed in a block fashion, with no information provided as to relative magnitudes of any measure within a given area or zone, much less relative magnitudes of temperature change.

Column 10, line 36 to column 11, line 3 and Figures 6 and 8 of Kuth illustrate another functionality of Kuth. In particular, the display of Fig. 8 illustrates regions “TT” of tumor “T” in which tissue modifications have been caused by focused ultrasound. Regions of “healthy” tissue in which tissue modifications have been caused by focused ultrasound are designated as “TG.” Regions of tumor “T” in which no tissue changes have been caused are identified by the designation “UT.” All other illustrated regions are untreated, healthy tissue. In short, the display of Fig. 8 again only provides a block indication of healthy and tumorous tissue regions that are either treated or untreated. That is, no thermal information indicative of relative magnitudes of temperature change for each of an array of spatial locations throughout a tissue region of interest is depicted.

More generally in this regard, the entire Kuth reference is only concerned with the location or position of different regions, zones or areas in relation to a displayed body region image. For example, and as provided in column 1, lines 5-16, Kuth is broadly directed to a “means for displaying an image of a body region of the subject which is to be treated with the

focused acoustic waves” and “means for mixing a mark which indicates the position of the therapeutic effective region into the displayed image” (emphasis added). Further in this regard, attention is directed to analogous and even more probative language found at col. 2, lines 8-31 of Kuth. Indeed, nowhere in Kuth does Kuth provide for the obtainment and display of thermal information indicative of relative magnitudes of temperature change at an array of spatial locations throughout a tissue region. Rather, and as noted above, regions, areas or zones in Kuth are displayed on a block-basis wherein the manner of display and information associated therewith is the same for all locations within a given region, area or zone.

In view of the foregoing, Applicant respectfully requests that the rejection of claims 1, 9 and 10 under 35 U.S.C. §102 be withdrawn. Applicant further submits that the various dependent claims dependent upon independent claim 1 are allowable for the same reasons as noted above, and additionally, because the further combinations defined thereby are not disclosed or suggested by the prior art.

Claims 2-8 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Kuth in view of Badger et al. (U.S. '436, hereinafter “Badger”). Applicant respectfully traverses this rejection. Claims 2-8 depend at least indirectly from independent claim 1 and thus all the comments made above with respect to Kuth apply to claims 2-8. Badger fails to resolve the above-described deficiencies of Kuth. For example, Badger fails to teach or suggest “generating thermal information in relation to each of said spatial locations by employing said first x-ray image and said at least a second x-ray image, wherein said thermal information is indicative of relative magnitudes of temperature changes for each of said spatial locations throughout said tissue region of interest,” as required by independent claim 1. Accordingly, even if Kuth and Badger were combined as proposed by the Office Action, the combination would not have taught

or suggested all of the claim limitations. Applicant thus respectfully requests that the rejection of claims 2-8 under 35 U.S.C. §103 be withdrawn.

**Conclusion:**

Applicant believes that this entire application is in condition for allowance and respectfully requests a notice to this effect. If the Examiner has any questions or believes that an interview would further prosecution of this application, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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